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Filing Date	08/25/03
First Named Inventor	Pierre Gauthier
Art Unit	
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Total Number of Pages in This Submission: 24

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Firm or Individual	PIERRE GAUTHIER
Signature	Pierre Gauthier
Date	February 10, 2004

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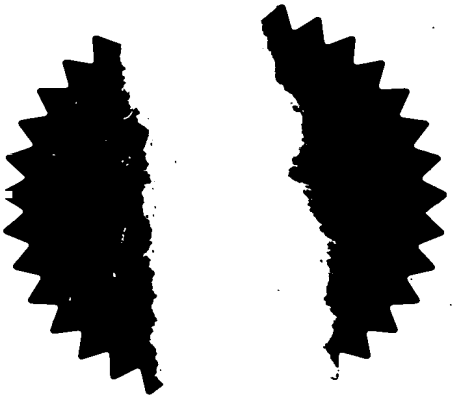

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11. I/~~We~~ request the grant of a patent on the basis of this application.

Signature Pierre Gauthier Date 19-08-2002

PIERRE GAUTHIER

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1. Your reference

9066-1

2. Patent application number
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3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

PIERRE GAUTHIER
32, BELLERIVE
ST-CHARLES BORROMEE, QUEBEC
J6E 8A4
CANADA

Patents ADP number *(if you know it)*

CUSTOMER ACCOUNT NUMBER: C05193

If the applicant is a corporate body, give the country/state of its incorporation

8451288001

4. Title of the invention

METHOD AND DEVICE FOR PREPARING TISSUES SECTIONS

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

INVENTION QUEBEC INC.
c/o DELEGATION GENERALE DU QUEBEC
59, PALL MALL
LONDON, ENGLAND
SW1Y 5JH

3962313001

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6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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See note (d))

I, Pierre Gauthier

C/O Invention Quebec Inc.
4101 Jarry St. East, Suite 307
Montreal, Quebec, Canada
H1Z 2H4

do hereby declare this invention to be described in the following statement:

METHOD AND DEVICE FOR PREPARING TISSUE SECTIONS

FIELD OF THE INVENTION:

The present invention relates to the general field of method and devices for preparing tissue samples and is particularly concerned to a method and device for the preparation of tissue sections incidental to the Mohs tissue surgical technique.

BACKGROUND OF THE INVENTION:

Surgical removal or biopsy of a tissue specimen for histologic examination is commonly used as a diagnostic tool for helping in establishing a precise diagnosis. Typically, when a lesion is suspected or known to be malignant, the entire mass of the lesion is preferably excised. Also, an examination technique is preferably further employed in which the tumor margin surface area is examined. The examination technique typically involves microscopic screening of the exterior surface area of the tumor mass for the presence of malignant cells to ensure that all such cells have been removed.

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Tumor margin surface area examination is practiced effectively and enhances the likelihood of complete removal of all cancerous cells of a localized malignancy. If it is estimated that the removal of the malignancy is not complete, a method may be used to precisely identify the location of any residual malignancy for subsequent removal or, when it is not possible to remove the malignancy through surgery, radiation therapy can be used.

One particularly popular surgical technique for removing skin tumors such as cutaneus malignancies and certain major carcinomas is the so called Mohs surgical technique developed by Frederic E. Mohs. The Mohs technique also involves evaluating thin sections or slices of the removed tissue under a microscope.

The Mohs tissue surgical technique involves excising a tissue sample that includes the skin tumor to be removed. Typically, the surface of the excised tissue to be inspected later on has a generally curved bowl-shaped surface resulting from the passage of scalpel below the surface of the skin. The generally parabolic cross section of the excised tissue block is typically marked for orientation purposes in order to allow the surgeon to determine where additional excisions must occur should the results of an inspection of a microscopic section of the tissue sample indicate that the tumor has spread beyond the excised tissue sample.

For the Mohs surgical technique to be successful, high quality horizontally cut frozen tissue sections must be produced and microscopically review to determine whether any residual tumor has spread beyond the tissue sample. In order for the high quality horizontally cut frozen tissue sections to be obtained, the excised tissue block having a generally parabolic cross sectional configuration must be converted to a tissue block having a generally planar cross sectional configuration. The conversion of the cross section from a curved to a generally planar configuration is

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necessary in order to obtain successful cryostatic sectioning. Indeed, in order to obtain high quality horizontally cut frozen tissue sections, the cutting tool must be provided with a generally planar surface generally parallel to the path of relative movement between the cutting knife and the specimen. This ensures sections of generally uniform thickness suitable for microscopic examination.

The cutting tool used for slicing the excised tissue in thin slices or sections is often referred to as a microtome. The microtome is, in turn, typically located in a refrigerated unit called a cryostat, capable of maintaining an internal temperature of -20° C. or less.

Typically, in order to enable slicing of the excised tissue, the latter is mounted on a cryostat chuck with the planar or flattened surface of the excised tissue exposes and perpendicular to the longitudinal axis of the cryostat chuck. Conventional cryostats are provided with chuck fixtures into which the chuck and tissue sample mounted thereon can be placed to allow the cryostat to cut the tissue sample into frozen section having a thickness of a few micrometers.

Once the sections have been sliced, they may be placed on a microscope slide prior to being stained by dipping the slide in various dye solutions and in solvents. Once the desired amount of staining is obtained, a covering substance such as a clear glue-like substance such as "Baume du Canada" is used to attach a thin layer of glass called a coverslip. Dying of the tissue slices enables a skilled person to determine with relative accuracy whether carcinomas cells are not present in the section being examined.

Although Mohs technique is quite useful, some of the steps accomplished through prior art methods and devices for performing the Mohs techniques suffer from numerous drawbacks. One of the difficulty associated with the Mohs technique

is that in order to obtain a tissue slice that includes the entire flattened, formerly bowl-shaped surface, including the epidermal periphery thereof, the plane in which the flattened formerly bowl-shaped surface lies must be substantially parallel to the plane in which the cryostat knife moves relative to the tissue sample.

With conventional methods of performing the Mohs surgical technique, the excised bowl-shaped tissue sample is typically positioned on the supporting surface so as to form a generally convex configuration. Hence, the deepest tissue section, or the bottom of the bowl, point upwardly relative to the supporting surface.

In order to flatten the inverted bowl-shaped tissue sample small lacerations are sometimes performed with the help of a scalpel or other cutting tool. Since the tissue sample is positioned in an inverted bowl-shaped configuration, the lacerations are often performed on the deepest part of the excision providing crucial information. Laceration of this crucial area of the excised tissue may potentially lead to difficult interpretation of the results. Also, the need for inverting the orientation of the excised tissue is both tedious and time consuming. It may also lead to manipulation errors.

If the planar surface of the formerly bowl-shaped surface is not parallel to the path of relative movement between the cryostat knife and the tissue sample, the first section performed by the cryostat knife may not include all of the formerly bowl-shaped surface.

In such situations, the surgeon must review subsequent deeper sections until a determination can be made that all of the formerly bowl-shaped surface has been evaluated. This can be a time consuming effort since each section must be stained and microscopically examined and interpreted by the surgeon before determination can be made as to whether further incision of tissue is necessary.

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If a tumor is encountered prior to the first section being completed, the result interpretation may be falsely positive requiring an additional excision of tissue sample. This additional excision may potentially lead to unnecessary injury of adjacent vessels, nerves or the like.

Furthermore, if the excised tissue sample is folded unto itself, the folded section may contain tumorous cells leading to falsely negative results. Accordingly, there exists a need for an improved method and device for tissue preparation in the context of tissue excisions such as Mohs micrographic surgery excision technique. Advantages of the present invention include that the proposed method and device allows the excised tissue sample to be properly flattened and remain integrally complete. The method and device allows the excised tissue sample to be initially manipulated by the surgeon with reduced needs of manipulation by technicians or other personnel leading to decreased risks of manipulation errors. Also, the proposed method and device allows the first sections performed by the cryostat knife to include all of the formerly bowl-shaped surface. This, in turn, substantially decreases the time, cost and effort required for satisfactorily performing the Mohs surgical technique.

Furthermore, the proposed device is designed so as to be easily manufacturable using conventional forms of manufacturing so as to provide a device that will be economically feasible, long lasting and relatively trouble-free in operation.

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BRIEF DESCRIPTION OF THE DRAWINGS:

An embodiment of the present invention will now be disclosed, by way of example, in reference to the following drawings in which:

FIGURE 1: in a schematic perspective view, illustrates a tumor mass being excised from a layer of skin using a scalpel knife;

FIGURE 2: in a schematic perspective view, illustrates an initial piece of tissue containing a tumor mass being removed from the skin of an intended patient;

FIGURE 3: in a schematic perspective view, illustrates a marginal tissue sample located adjacent the location of the excised tumorous mass being excised using a conventional scalpel blade;

FIGURE 4: in a schematic perspective view, illustrates the marginal tissue sample being removed from the skin of a patient;

FIGURE 5: in a schematic perspective view, illustrates a bowl-shaped marginal tissue sample having been removed from the skin of a patient;

FIGURE 6: in a schematic perspective view, illustrates the marginal tissue sample shown in FIG. 5 having been sectioned into four (4) sample pieces;

FIGURE 7: in a schematic perspective view, illustrates a sample section adapted to be examined using the method and device in accordance with the present invention;

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FIGURE 8: in a schematic perspective view; illustrates the tissue section shown in FIG. 7 having been inverted and positioned on a supporting surface, the inversion step being part of a prior art method;

FIGURE 9: in a perspective view, illustrates an object supporting component used both by prior art methods and the method and device in accordance with the present invention;

FIGURE 10: in a perspective view, illustrates the object supporting component shown in FIG. 9 having a surface thereof coated with a coating gel;

FIGURE 11: in a schematic perspective view, illustrates the object supporting component shown in FIGS. 9 and 10 with a sample section mounted thereon in an inverted configuration, the mounting of the sample section in an inverted configuration being part of a step of a prior art method;

FIGURE 12: illustrates the combination of the object supporting component, gel and sample section shown in FIG. 11 coated with a coating of covering gel, the step shown in FIG. 12 being part of a prior art process;

FIGURE 13: in a schematic perspective view, illustrates a supporting disc part of a device in accordance with an embodiment of the present invention having a sample section mounted thereon, the sample section remaining in its non-inverted generally concave configuration;

FIGURE 14: in a schematic perspective view, illustrates the combination shown in FIG. 13 with the tissue sample having incisions made on the upper surface thereof;

FIGURE 15: in a perspective view, illustrates a device in accordance with an embodiment of the present invention;

FIGURE 16: in a partial longitudinal cross sectional view with sections taken out, illustrates some of the components of the device shown in FIG. 15;

FIGURE 17: in a partial longitudinal cross sectional view with sections taken out, illustrates a tissue sample resting on a section of the device shown in FIGS. 15 and 16 about to be put into contact with an object supporting component;

FIGURE 18: illustrates the combination of the device, tissue mounted thereon and object supporting component being attached together by a cover, part of the device in accordance with an embodiment of the present invention;

FIGURE 19: in a partial side elevational view, illustrates a tissue sample being removed from the device in accordance with the present invention;

FIGURE 20: in a perspective view, illustrates the sample mounted on the object supporting component being sliced into examination slices.

DETAILED DESCRIPTION:

FIGS. 1 through 7, illustrate the initial steps for performing the Mohs micrographic surgery technique common to both the prior art processes and the method in accordance with the present invention. FIG. 1, illustrates a tumorous mass (10) of malignant cells being excised from an adjacent area of healthy skin (12) by the blade (14) of a conventional surgery scalpel. FIG. 2, illustrates the bulk of the

tumorous mass (10) with a marginal section (16) thereof being removed from an underlying and peripherally adjacent marginal area (18) containing tumorous islands (20). As is well known in the art, the bulk of the tumorous mass (10) will be sent for histologic examination without freezing.

FIG. 3, illustrates the marginal section (18) encompassing the entire wound bed being excised from around and underneath the wound created by the removal of the tumorous mass (10). The marginal section being removed forms a layer of tissue typically excised using a surgical scalpel (14') making an incision (22) through the skin at an angle typically of between 30 and 45° in order to create a gradual transition between the lateral and deep margins.

FIG. 4, illustrates a marginal sample (26) being removed from the skin of the patient. FIG. 5, illustrates the generally bowl-shape of the marginal sample (26) having been completely removed from the skin of the patient.

FIG. 6, illustrates the bowl-shape of marginal tissue sample (26) having been divided into quadrants. The divisions are typically marked with tissue dyes or other means for later identification. Typically, the sectioned surfaces are dyed from the epithelial border to the apex.

FIG. 7, illustrates a typical section of marginal tissue sample having a generally concave configuration and defining an epithelial border (28) and an apex (30). The sample section (32) is shown containing a tumorous island (34). FIG. 8, illustrates the sample section (32) having been placed on a supporting surface (36) in an inverted generally convex configuration with the deeper surgical margin (38) positioned away from the supporting surface (36). The deeper surgical margin (38) being the surface that will be studied would ideally remain generally unaltered. However, in order to generally flatten the sample section (32), prior art techniques

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often make small incisions into the deeper surgical margin (38). Hence, FIG. 8 illustrates a step of a conventional method that is not used with the method in accordance with the present invention.

FIGS. 8 through 12 illustrate steps part of a prior art method for preparing the tissue sample (32) for cryostat slicing. The prior art method involves coating the supporting surface (40) of a conventional sample supporting component (42) with a suitable first layer (46) of coating gel. The conventional coating gel typically used is a so-called OCT fluid. The OCT fluid is a clear, tissue mounting fluid such as sold under the brand name "Tissue Tek II OCT Compound" by Miles Laboratories Inc. The sample supporting component (42) or chuck is typically provided with a flange (44) extending from the peripheral edge of the supporting surface (40). Also, the supporting surface (40) is typically provided with a generally friction enhancing texture.

As shown in FIG. 11, the sample section (32) is then typically positioned on the first layer (44) of gel coat in a generally convex inverted position with the deep marginal section (38) thereof positioned away from the supporting surface (40). As shown in FIG. 12, the sample section (32) is then covered with a second layer (46') of OCT gel.

FIGS. 13 through (20), illustrate some of the steps and components part of the method and device in accordance with the present invention. FIG. 13, illustrates the sample section (32) mounted on a supporting disc or plate (48). The sample section (32) is shown mounted on the plate (48) in a generally convex configuration with its deep marginal section (38) in abutting contact with the supporting plate (48). The disc or plate (48) is typically made out of a suitable material such as stainless steel or glass coated with a suitable layer of polymeric material.

FIG. 14, illustrates the sample section (32) positioned on the supporting plate (48) and having incisions made thereon in order to facilitate flattening of the sample section (32). The superficial incisions (50) are made in the shallow marginal section (52) as opposed to the deeper marginal surface (38) leaving the deeper marginal section or surface (38) unaltered. The user can also easely verified that the sample (32) is well flaten on the suporting plate (48) by alining his eyesight to the disk surface, to take a sight of the peripheral contact surface of the apex (30).

Referring now more specifically to FIGS. 15 and 16, there is shown some of the components of a device (54) in accordance with an embodiment of the present invention. The device (54) includes a piston component (56) slidably and substantially fittingly mounted within a generally cylindrical piston sleeve (58) for reciprocal movement therein. The piston component (56) defines a generally flat piston supporting surface (60).

A piston biasing means (62) is provided for biasing the piston component (56) axially within the piston sleeve (58) as indicated by arrow LXIV in FIG. 16. The piston component (56) is biased so as to slide between a retracted configuration shown in FIGS. 16 through 18 wherein the piston supporting surface (60) is retracted within the piston sleeve (58) and a piston extended configuration shown in FIG. 19 wherein the piston supporting surface (60) protrudes outwardly from the piston sleeve (58).

The piston sleeve (58) defines a sleeve inner surface (64) and a sleeve flange (66) extending generally integrally and coaxially therefrom. The sleeve inner surface (64) and the sleeve flange (66) define a sleeve ledge or shoulder (68) extending generally perpendicularly therebetween.

The cap component (70) is mountable over the sleeve component (58) adjacent the sleeve flange (66). Both the cap component (70) and the sleeve component (58) are provided with releasable locking means for locking the cap component (70) in a predetermined axial relationship relative to the sleeve component (58). The releasable locking means typically includes a first cap thread (72) extending from the outer surface of the sleeve component (58) adjacent the sleeve flange (66) and a second cap thread (74) extending from the inner surface of the cap component (70) for cooperating threadable engagement with the first cap thread (72).

The cap component (70) includes a cap flange (76) extending from a cap abutment surface (78). The cap abutment surface (78) is provided with a cap aperture (80) extending therethrough. The cap aperture (80) is intended to allow through flow of products such as freezing vapors.

The piston biasing means may take any suitable form. In at least one embodiment of the invention, the piston biasing means includes a biasing stem (82) having a stem attachment means (84) for attachment to the piston component (56) generally adjacent the piston supporting surface (60). Typically, the biasing stem (82) is provided with a stem thread formed thereon for threadable engagement with a sleeve thread (86) formed on the inner surface of a stem aperture (88) extending through the sleeve component (58) opposite the sleeve flange (66). Typically, the piston component (56) is provided with stem attachment threads (not shown) for receiving the distal end of the biasing stem (82).

The biasing stem (82) may further be provided with a stem plate (90) attached thereto and extending in a generally perpendicular relationship relative to the longitudinal axis of the biasing stem (82). The stem disc (90) is typically provided with the concave recesses (92) formed on its peripheral edge for facilitating

prehension and manipulation of the stem disc (90). Also, the stem disc (90) is typically configured and sized for allowing the stem disc (90) to act as a base for supporting the combination of the piston component (56) and the sleeve component (58) in a generally upright configuration such as shown in FIG. 16 when rested on a supporting surface (94).

In use, the device (54) is initially subjected to low temperatures until it reaches a temperature substantially in the range of -24 to -26° C. As illustrated in FIG. 17, the supporting plate or disc (48) with the sample section (32) mounted thereon is then abuttingly rested on the piston supporting surface (60). A layer of OCT coating gel (96) is then applied over the sample section (32).

A conventional object supporting component or chuck (42) is then lowered in an inverted configuration over the layer of gel (96). Excess gel compressed by the chuck (42) is allowed to escape laterally between the sleeve flange (66) and the supporting component flange (44) as indicated by arrows XCVIII in FIG. 17.

As illustrated in FIG. 18, the chuck (42) is lowered until the peripheral edge of the object supporting surface (40) abuttingly contacts the sleeve ledge or shoulder (68). The sleeve ledge or shoulder (68) hence prevents the chuck (42) from crushing the tissue sample section (32). Also, the sleeve ledge or shoulder (68) is configured, sized and positioned so as to ensure that the supporting surface (40) of the chuck (42) is in a generally parallel relationship relative to the supporting plate (48).

The cap component (70) may optionally be threaded unto the sleeve component (58) for releasably locking the chuck (42) into the compressing configuration shown in FIG. 18. The cap aperture (80) allows a freezing vapor to be vaporized on the chuck (42) for freezing the supporting surface (40) of the latter. Typically, the freezing operation lasts for approximately 20 to 30 seconds. The cap

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component (70) may then be removed. Once the cap component (70) is removed, rotation of the biasing stem (82) biases the piston component (56) towards its extended configuration, shown in FIG. 19, wherein the supporting plate (48) and other objects and components mounted thereon protrude outwardly from the sleeve component (58).

As illustrated in FIG. 20, the supporting plate or disc (48) may be easily removed from the mass (100) formed by the frozen gel layer (96) and adjacent sample section (32). The mass (100) may then be sliced using a conventional cryostat knife into thin layers typically having a thickness substantially in the range of 5 microns. The layers (102) are hence obtained through a set of quick, easy and ergonomic steps.

Signed: Pierre Gauthier

Pierre Gauthier, Inventor.

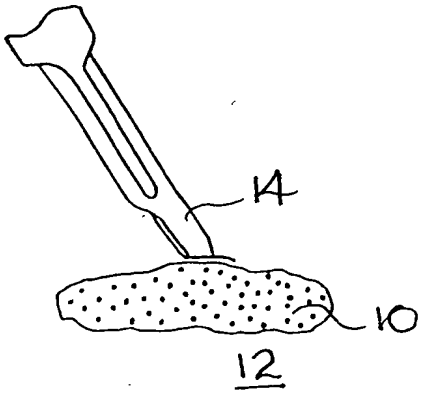

Fig. 1

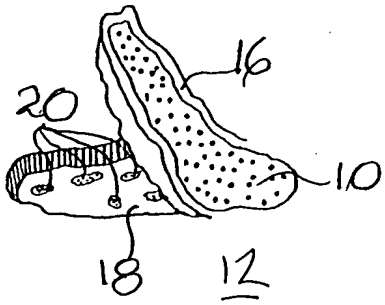

Fig. 2

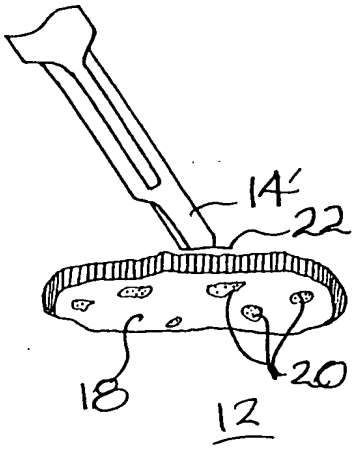

Fig. 3

Pierre Gauthier
INVENTOR

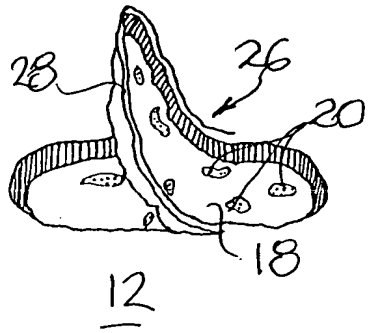

Fig. 4

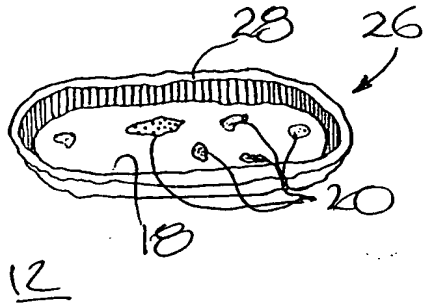

Fig. 5

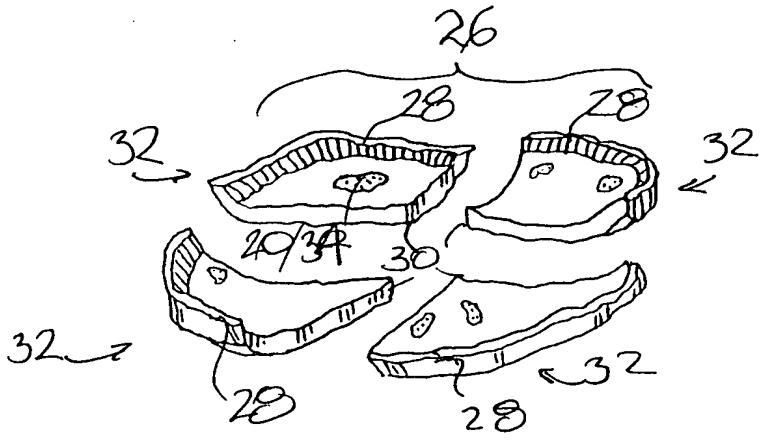

Fig. 6

Pierre Gauthier
INVENTOR

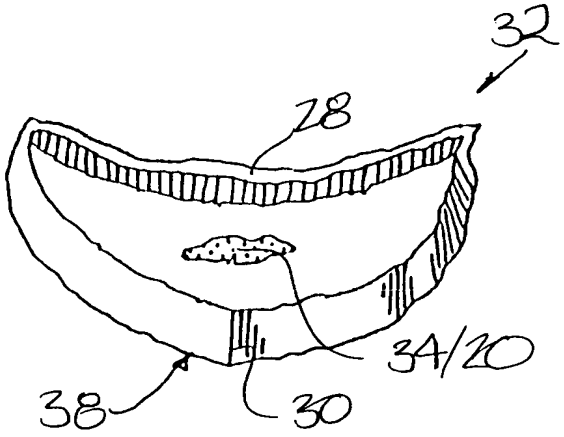

Fig. 7

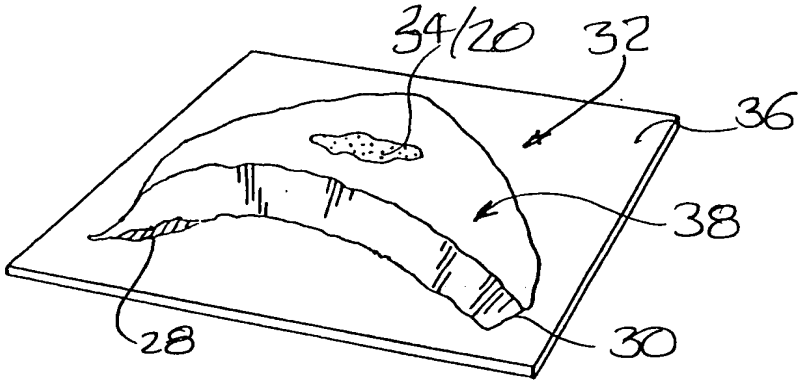

Fig. 8

Pierre Gauthier
INVENTOR

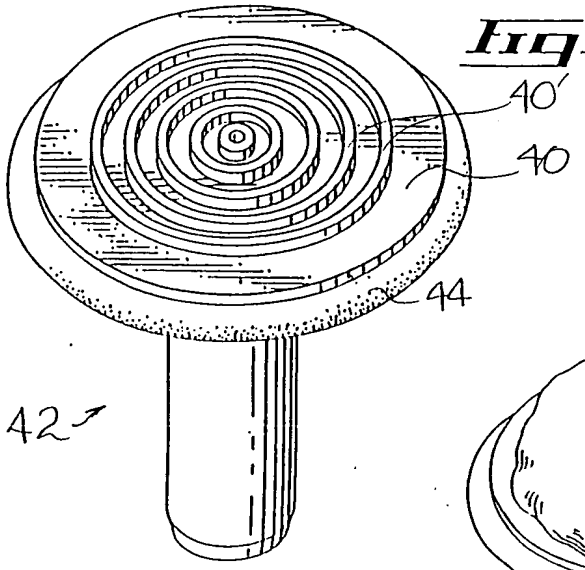

Fig. 9

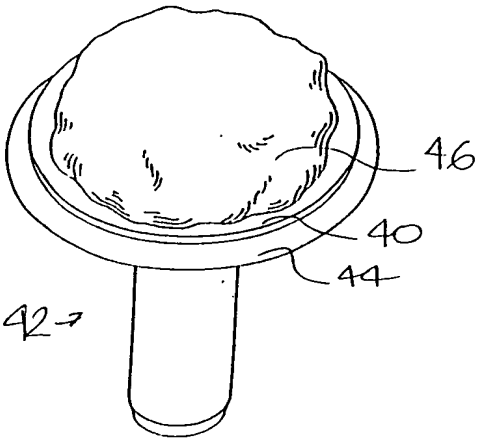

Fig. 10

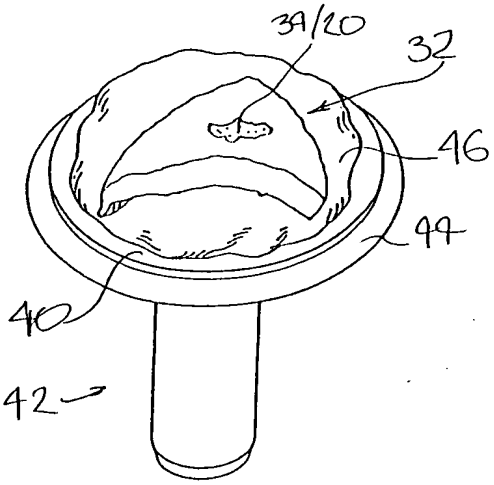

Fig. 11

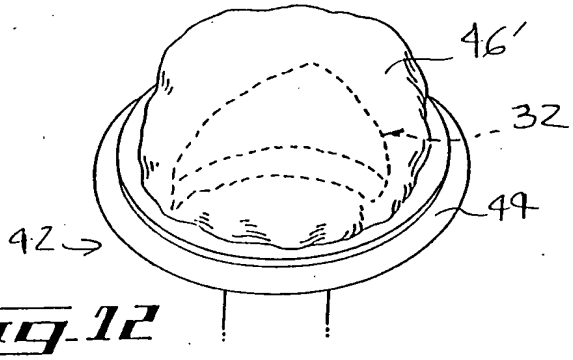

Fig. 12

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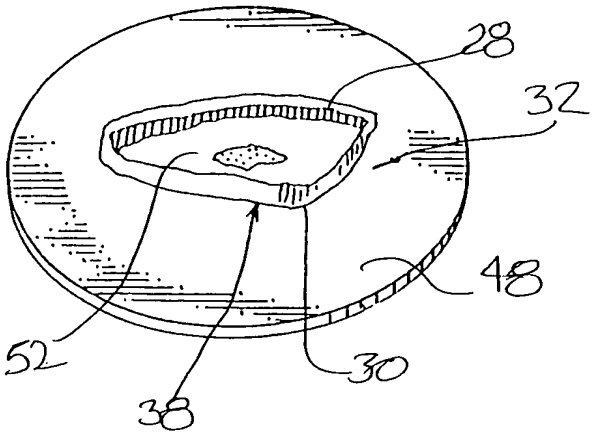

Fig. 13

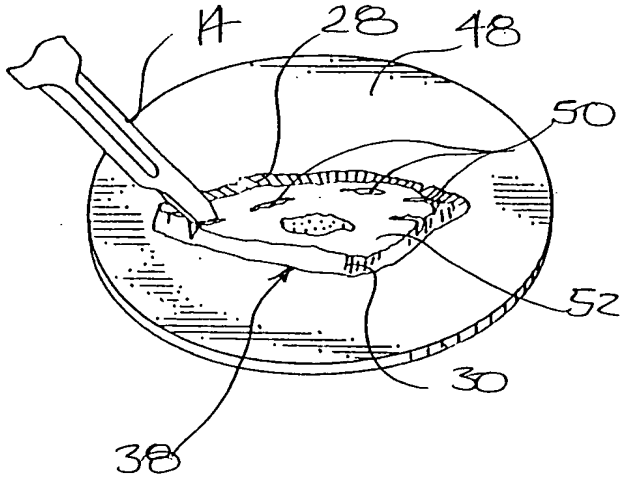

Fig. 14

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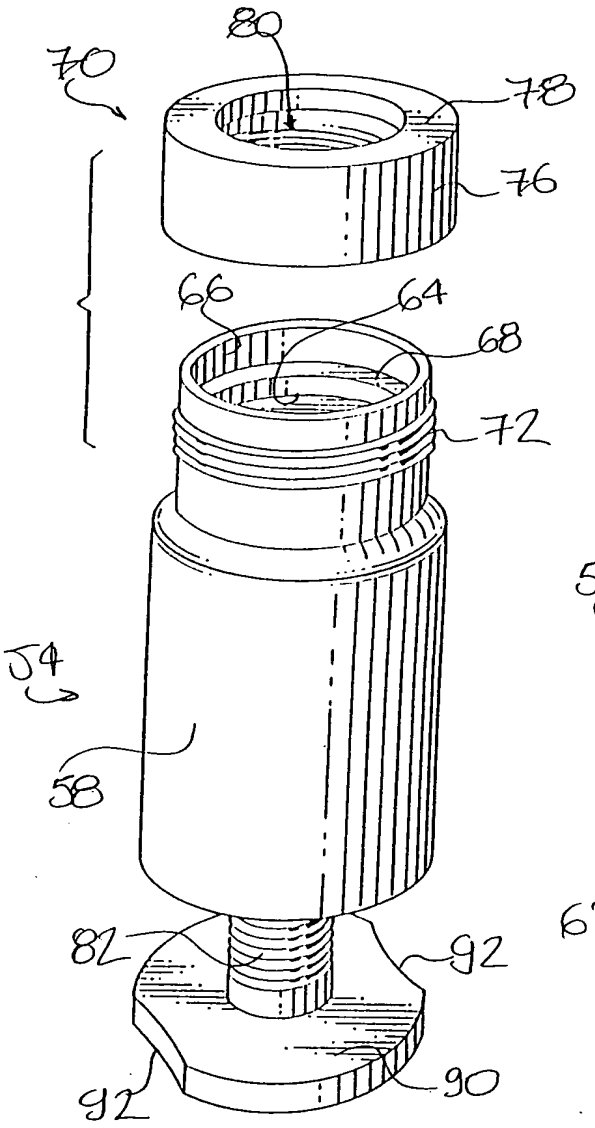
Fig. 15



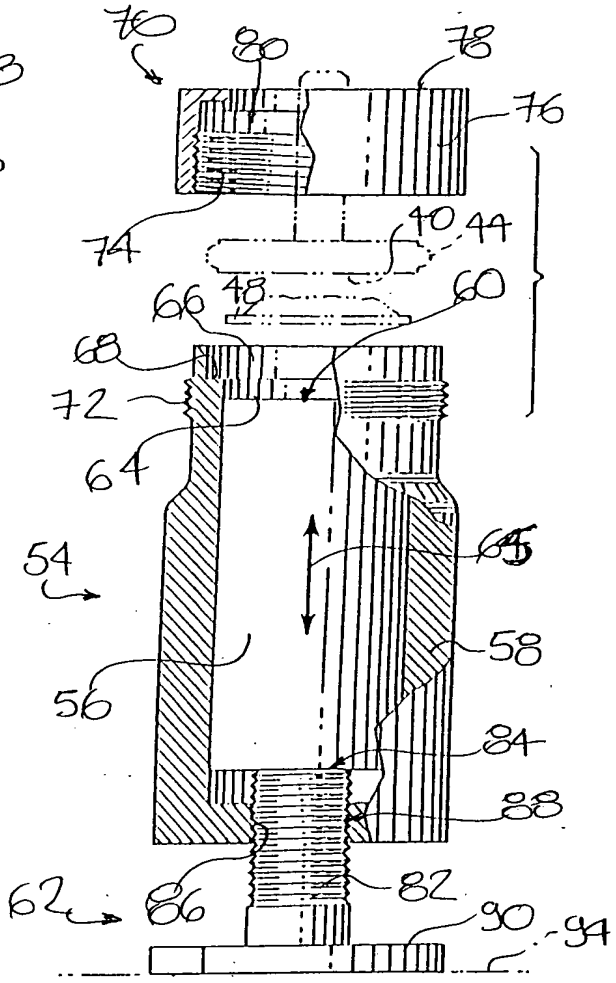


Fig. 16

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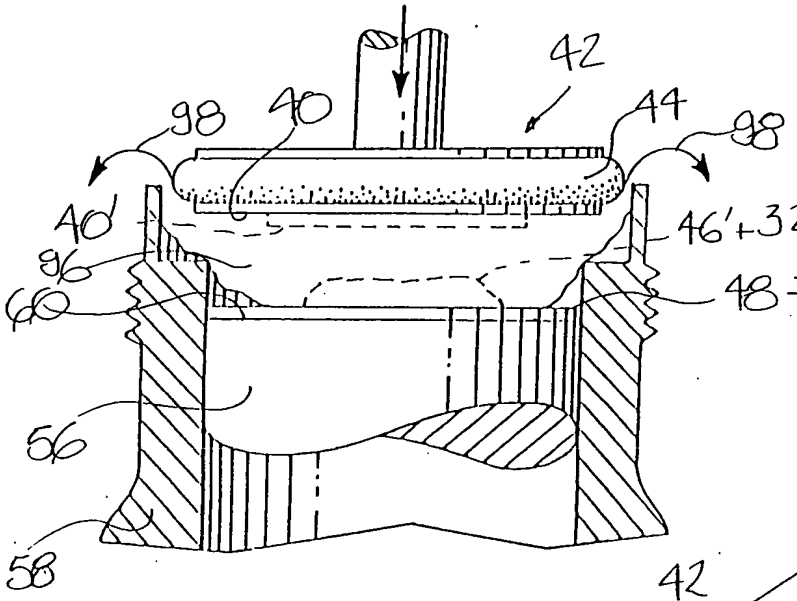

Fig. 17

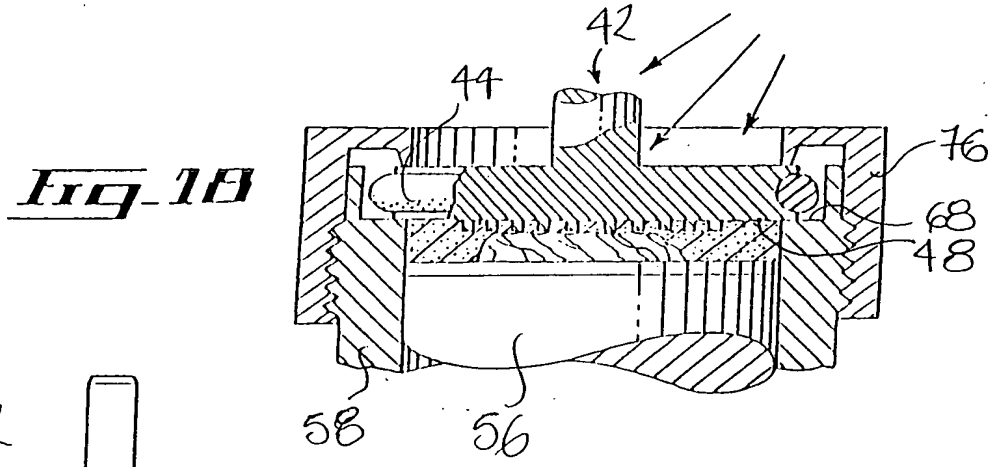

Fig. 18

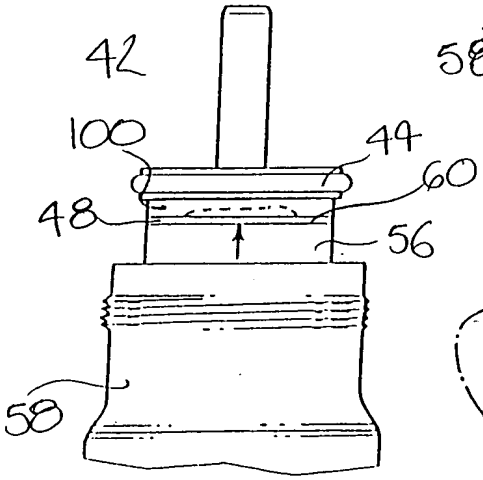

Fig. 19

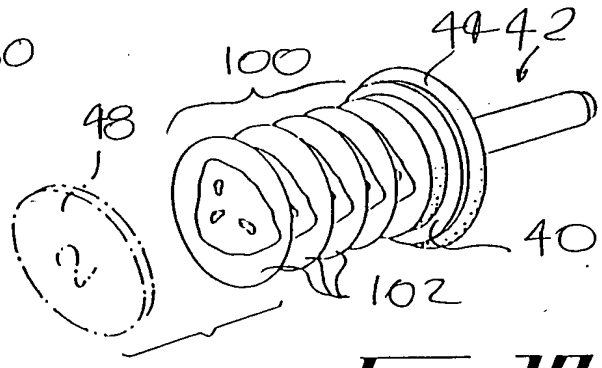

Fig. 20

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INVENTOR